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10/086,253	03/01/2002	Barbara A. Rincavage	RINCAVAGE-1	4031

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EXAMINER	
RINES, ROBERT D	
ART UNIT	PAPER NUMBER
3623	
MAIL DATE	DELIVERY MODE
12/16/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/086,253	RINCAVAGE ET AL.	
	Examiner	Art Unit	
	R. David Rines	3623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 October 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

[1] A request for continued examination under 37 CFR 1.114 was filed in this application after a decision by the Board of Patent Appeals and Interferences, but before the filing of a Notice of Appeal to the Court of Appeals for the Federal Circuit or the commencement of a civil action. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 30 October 2009 has been entered.

Notice to Applicant

[2] This communication is in response to the Amendment and the Request for Continued Examination (RCE) filed 30 October 2009. The present RCE/Amendment was filed after the Decision of the USPTO Board of Patent Appeals and Interferences issued 3 September 2009. Claims 1-20 have been cancelled. Claims 21-40 have been added. Claims 21-40 are pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

[3] Claims 31-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Independent claim 31 is directed to " a prescription fulfillment system..." and accordingly appears to be directed to a machine or apparatus (i.e., "system"). However, the body of the claim fails to identify hardware components and/or elements such that a system structure is evident. Claim 31 identifies "a processing center" as a system component/structure. A "processing center" is reasonably interpreted to be a physical location where prescriptions are processed and further, the term "processing center" does not inherently denote specific hardware such that a machine or apparatus is reasonably defined. Accordingly, it is not clear what structure the recited "processing center" defines. Appropriate correction is required.

Dependent claims 32-40 inherit the deficiencies of claim 31 by dependency and, when analyzed in the same manner described above with respect to claim 31, clearly define a system structure. Claims 32-40 are rejected under 35 U.S.C. 112, second paragraph as well.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requires of this title.

[4] Claims 21-30 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Under the statute, the claimed invention must fall into one of the four recognized statutory classes of invention, namely, a process (or method); a machine (or system); an article of manufacture; or a composition of matter. The latter three categories define "things" or "products" while a process consists of a series of steps or acts to be performed.

In order for a process to be considered statutory under 35 U.S.C. 101, the claimed process must either: (1) be tied to another statutory class (such as a particular apparatus) or (2) transform underlying subject matter (such as an article or materials). *Diamond v. Diehr, 450 U.S. 175, 184 (1981); Parker v. Flook, 437 U.S. 584, 588 n.9 (1978); Gottschalk v. Benson, 409 U.S. 63, 70 (1972).* If neither of these requirements is met by the claim, the method is not eligible for patent under 35 U.S.C. 101 and is non-statutory subject matter.

Independent claim 21 does not present a substrate or material such that element (2), the transformation of underlying subject matter, would be applicable.

Independent claim 21 is directed to a "...prescription fulfillment method...". The method steps recited in the body of the claim fail to identify a specific machine or apparatus employed in the method such that the method is clearly tied to specific machine or apparatus.

While Examiner recognizes that the recited method steps refer to a "...processing center...", a "processing center" does not inherently denote a specific machine or apparatus. A processing center, is reasonably interpreted to be a physical location.

Dependent claims 22-30 inherit the deficiencies of claim 21 by dependency and, when analyzed in the same manner described above with respect to claim 21, also fail to positively recite another statutory class of invention. Examiner recognizes that dependent claims 21-30 refer to features and functions which may utilize a specific machine or apparatus (e.g. biometric identifier, voice imprint etc.), however, a specific machine or apparatus which enables the recited functions is not positively identified. Therefore, claims 22-20 are also rejected under 35 U.S.C. 101 as being directed to non-statutory subject matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

[5] Claims 21-22, 27-30, 31-32, and 37-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Denny (United States Patent Application Publication #2004/0107117) in view of Borsand et al. (United States Patent Application Publication #2003/0074225).

As per (newly added) claim 21, Denny discloses a prescription fulfillment method, comprising; entering an unfilled prescription prescribed by a physician or medical service provider into a processing center wherein the prescribed prescription comprises at least medication brand or dosage (Denny; paragraphs [0010] [0027] [0030] [0031] [0064]); retrieving an unfilled prescription from the processing center (Denny; paragraphs [0011] [0012] [0032] [0035] [0036] [0064]); filling the prescribed prescription by a pharmacist (Denny; paragraphs [0031] [0032] [0036] [0049] [0063] [0064]), wherein the filled prescription is different from the retrieved prescription in respect of at least one of medical brand and dosage; entering the filled prescription into the processing center in fulfillment of the prescribed prescription for review by

the prescribing physician or medical service provider (Denny; paragraphs [0031] [0032] [0036] [0049] [0063] [0064]).

While Denny provides for the pharmacist inputting information representative or indicative of a prescription to be filled (Denny; paragraph [0035]) and subsequently provides for the pharmacist inputting a code indicating that a prescription has been filled into the host system (Denny; paragraph [0041]), Denny fails to specifically indicate that the pharmacist enters filled prescription data that includes pharmaceutical type, quantity, cost or other information and "wherein the filled prescription is different from the retrieved prescription in respect of at least one or medical brand and dosage..".

However, as is evidenced by Borsand et al., it is well known in the prescription fulfillment art for the pharmacist to record or enter into a database, information regarding the specifics of a filled prescription including cost, drug type, and quantity administered to the patient. Accordingly, Borsand et al. teach a method wherein said filled prescription data includes information for said presented pharmaceutical type and said presented quantity and "wherein the filled prescription is different from the retrieved prescription in respect of at least one or medical brand and dosage..". (Borsand et al.; paragraphs [0005] [0040] [0056] [0064] [0086] [0118] *see electronic representation of filled prescription).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the teachings of Denny with those of Borsand et al. Such combination would have resulted in a system and method that enabled the entry of prescription information including prescribed drug and dosage level prescribed to a patient, by a physician, into a host system (Denny; Abstract). Such a method/system would have further provided for the retrieval of the prescribed drug and dosage level information from the host system, by a pharmacist, for the purpose of filling the prescription for the patient (Denny; Abstract). Additionally, such a system/method would have enabled the pharmacist to enter information indicating that the prescription had been filled into the host system for the review of the prescribing physician (Denny; paragraphs [0035] [0041] [0053]). Lastly, such a method would have been enabled by a integrated system in which the payor, PBM, pharmacy, and provider access and manipulate the same information, including prescribed drug, quantity/dosage, refills, cost, and reimbursement rules (Borsand et al.; paragraphs [0040] [0064]). The motivation to combine the teachings would have been to enable a provider to monitor the filling of a prescription such that the prescription can be cancelled in the event of fraud, abuse, or mistakes, such as a pharmacist filling a prescription at half strength but twice the volume and cost (Borsand et al.; paragraphs [0005] [0120]).

As per (newly added) claim 22, Denny discloses a method further comprising comparing the different medication brand or doasage of the unfilled prescription with the filled and different medication brand or dosage and generating a warning of the different medical brand or dosage (Denny; paragraph [0053]).

As per (newly added) claim 27, Denny discloses a method comprising registering medical service professionals authorized to access a database associated with the processing center (Denny; paragraphs [0027] [0029] [0043] [0047]).

As per (newly added) claim 28, Denny discloses a method wherein entering the filled medication generates a warning signal to the prescribing physician or medical service provider (Denny; paragraph [0053]).

Regarding claim 28, Denny discloses a check for prescription data validity and subsequent messaging to the physician, Denny fail to explicitly recite that the data check specifically check the contents of the filled prescription, i.e., dosage and brand.

However, as is evidenced by Borsand et al., it is well known in the prescription fulfillment art for the pharmacist to record or enter into a database, information regarding the specifics of a filled prescription including cost, drug type, and quantity administered to the patient. Accordingly, Borsand et al. teach a method wherein said filled prescription data includes “filled and different"

information (Borsand et al.; paragraphs [0005] [0040] [0056] [0064] [0086] [0118] *see electronic representation of filled prescription).

As per (newly added) claim 29, while Denny discloses a warning mechanism, Denny fails to specifically indicate that the warnings are sent to an insurance company.

However, Borsand et al. disclose a method wherein entering the filled prescription medication generates a warning signal to an insurance company (Borsand et al.; paragraphs [0005] [0034] [0120]-[0122] and Fig. 11).

NOTE: Borsand et al. provide a system and method that supports tracking pharmaceutical, prescription, and related information throughout the life cycle of the pharmaceutical or prescription (Borsand et al.; paragraph [0034]). Borsand et al. further specify that information tracking can be in a proactive and real-time manner (Borsand et al.; paragraph [0034]). Borsand et al. further teach that a purpose of proactive and real-time tracking of information is to identify instances of fraud or error, such as a pharmacist filling a prescription at half strength and half strength and twice the volume and cost (Borsand et al.; paragraph [0005]). Examiner's interpretation of the above noted teachings of Borsand et al. constitute a "warning" mechanism indicating that a pharmacist has failed to fill a prescription properly.

As per claim 30, Denny discloses a method wherein the processing center is accessed by the physician, medical service provider or pharmacist by a telecommunications link (Denny; paragraphs [0023] [0038]).

Regarding claims 22 and 27-30, the conclusions of obviousness and statements of motivation as discussed with regard to claim 21 above are applicable to claims 22 and 27-30 and are herein incorporated by reference.

Claims 31-32 and 37-40 substantially repeat the subject matter presented in method claims 21-22 and 27-30 system form. Accordingly, claims 31-32 and 37-40 are rejected as obvious in consideration of Denny in view of Borsand et al. for the reasons, conclusions of obviousness, and statements motivation as discussed above with respect to claims 21-22 and 27-30.

[6] Claims 23-26 and 33-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Denny and Borsand et al. as applied to claims 1 and 12 above, and further in view of Keresman, III et al. (United States Patent Application Publication #2001/0047281).

Regarding claims 23-26, while Denny teaches authenticating and identifying provider and pharmacist systems accessing the host system (Denny; paragraph [0043]), Denny fails to specifically teach biometric identification as part of the security protocol. Borsand et al. fail to disclose biometric authentication.

However, as evidenced by Keresman, III et al., the use of biometric identification of registered doctors, pharmacies, and other participants is well known in the prescription drug fulfillment art (Keresman III et al.; paragraphs [0008] [0009] [0015] [0050] [0056]).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the teachings of Denny and Borsand et al., as applied to claim 1 and 12 above, with those of Keresman, III et al. with the intention of determining that the requesting system is a valid system by using password protection or other security methods known in the art (Denny; paragraph [0043]). The motivation to combine the teachings would have been to employ a well-known security protocol to provide a suitable degree of security, which prevents unauthorized access to a patient's confidential medical and pharmaceutical records (Keresman, III et al.; paragraph [0004]).

Claims 33-36 substantially repeat the subject matter presented in method claims 23-26 in system form. Accordingly, claims 33-36 are rejected as obvious in consideration of Denny in view of Borsand et al. for the reasons, conclusions of obviousness, and statements motivation as discussed above with respect to claims 23-26.

Response to Remarks

Applicant's remarks filed 30 October 2009 have been fully considered but they are not persuasive. The remarks will be addressed below in the order in which they appear in the noted response.

Applicant remarks that the combination of Denny, Keresman, and Borsand, does not describe the process defined by newly added claim 21 of present application.

Specifically, Applicant remarks:

"...prior art "yes" methods and systems (Denny, Keresman, and Borsand) do not provide for entering a filled prescription that is different with respect to brand or dosage...Denny, Keresman and Borsand do not teach entry of "different medication brand or dosage information into a processing center in fulfillment of a prescribed prescription..."

In response, Examiner respectfully disagrees and directs Applicant's attention to the teachings of Borsand. Specifically, Borsand et al. disclose the electronic representation of a filled prescription is generated in a substantially simultaneous manner with the filling of the prescription and the distribution of the prescribed pharmaceutical (Borsand et al.; paragraph [0084]). Borsand et al. additionally disclose that during prescription fulfillment at the pharmacy, the prescription is re-evaluated in terms of reimbursement rules and medical appropriateness and that if for any

appropriate business or medical reason the filling of a prescription should not occur, the pharmacist can cancel or potentially even modify the prescription as appropriate (Borsand et al.; paragraph [0087]). Borsand et al. further disclose that the pharmaceutical type and quantity are entered into the system as a matter of protocol during the generation of the prescription by a physician (Borsand et al.; paragraph [0064]). Examiner respectfully maintains that the electronic representation of the filled prescription data would convey any alteration (e.g. generic substitution) to the filled data as entered by the pharmacist.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to R. David Rines whose telephone number is (571)272-5585. The examiner can normally be reached on 8:30am - 5:00pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Beth Boswell can be reached on 571-272-6737. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/R. David Rines/
Examiner, Art Unit 3623